IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, and JANSSEN PHARMACEUTICALS, INC.,

Plaintiffs,

v.

AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., BRECKENRIDGE PHARMACEUTICAL, INC., INVAGEN PHARMACEUTICALS, INC., MICRO LABS LTD., MICRO LABS USA INC., MYLAN PHARMACEUTICALS INC., PRINSTON PHARMACEUTICAL INC., SIGMAPHARM LABORATORIES, LLC, TORRENT PHARMACEUTICALS, LIMITED, and TORRENT PHARMA INC.,

Defendants.

Civil Action No. 1:15-cv-902-RGA

MEMORANDUM OPINION

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March 3, 2017

ANDREWS, U.S. DISTRICT JUDGE:

Presently before the Court is the issue of claim construction of a single term in U.S. Patent No. 7,157,456 ("the '456 patent"). The Court has considered the Parties' Claim Construction Briefs. (D.I. 144, 156, 162, 168). The Court heard oral argument on March 3, 2017.

I. BACKGROUND

This suit arises from Defendants' filing Abbreviated New Drug Applications ("ANDA") for generic versions of Plaintiffs' anticoagulant, sold under the brand name XARELTO. (D.I. 144 at 6). Plaintiffs filed suit, alleging that the generic products that are the subjects of the ANDA filings would infringe a number of Plaintiffs' patents. (D.I. 1). The patents-in-suit claim compounds for use in treating thromboembolic disorders and methods of treatment using these compounds.

II. LEGAL STANDARD

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted). "'[T]here is no magic formula or catechism for conducting claim construction.' Instead, the court is free to attach the appropriate weight to appropriate sources 'in light of the statutes and policies that inform patent law.'" *SoftView LLC v. Apple Inc.*, 2013 WL 4758195, at *1 (D. Del. Sept. 4, 2013) (quoting *Phillips*, 415 F.3d at 1324) (alteration in original). When construing patent claims, a court considers the literal language of the claim, the patent specification, and the prosecution history. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977–80 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996). Of these sources, "the specification is always highly relevant to the claim construction

analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315 (internal quotation marks omitted).

"[T]he words of a claim are generally given their ordinary and customary meaning. . . . [Which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312–13 (citations and internal quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to [an] ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). "In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words." *Id.* at 1314.

When a court relies solely upon the intrinsic evidence—the patent claims, the specification, and the prosecution history—the court's construction is a determination of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). The court may also make factual findings based upon consideration of extrinsic evidence, which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Phillips*, 415 F.3d at 1317–19 (internal quotation marks omitted). Extrinsic evidence may assist the court in understanding the underlying technology, the meaning of terms to one skilled in the art, and how the invention works. *Id.* Extrinsic evidence, however, is less reliable and less useful in claim construction than the patent and its prosecution history. *Id.*

"A claim construction is persuasive, not because it follows a certain rule, but because it defines terms in the context of the whole patent." *Renishaw PLC v. Marposs Societa' per*

Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GMBH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (citation and internal quotation marks omitted).

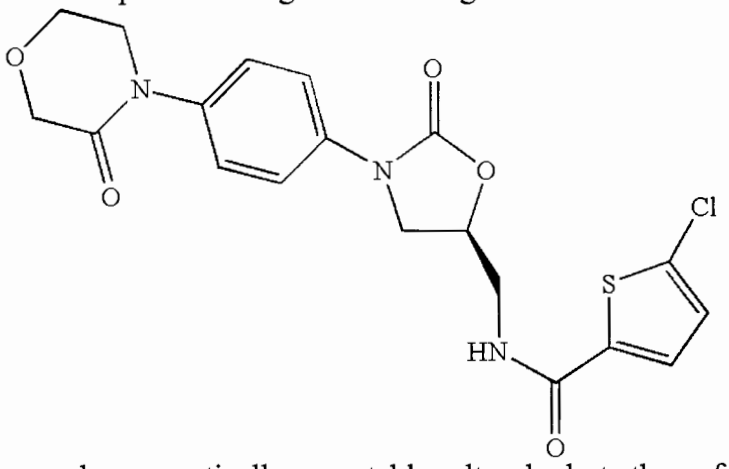
III. CONSTRUCTION OF DISPUTED TERMS

The '456 patent is directed to compounds and methods for treatment of thromboembolic disorders. The only disputed term appears in dependent claim 14, which reads as follows:

14. *The compound of claim 6 that is purified and isolated.*

('456 patent, claim 14) (disputed terms italicized). Independent claim 6, from which claim 14 depends, reads as follows:

6. The compound having the following formula



or a pharmaceutically acceptable salt or hydrate thereof.

('456 patent, claim 6).

1. "The compound of claim 6 that is purified and isolated."

   a. *Plaintiffs' proposed construction*: "The compound of claim 6 that is sufficiently free of impurities and any synthesis-related compounds to permit its use in a pharmaceutical composition. The claim does not exclude a pharmaceutical composition that contains the compound of claim 14 and one or more pharmacologically acceptable auxiliaries or excipients."

   b. *Defendants' proposed construction*: "The compound of claim 6 that is sufficiently free of impurities and any synthesis-related compounds to permit its use in a

pharmaceutical composition, including but not limited to compounds such as pharmacologically acceptable auxiliaries and excipients."

c. *Court's construction*: "The compound of claim 6 that is sufficiently free of impurities and any synthesis-related compounds to permit its use in a pharmaceutical composition. The claim does not exclude a pharmaceutical composition that contains the compound of claim 14 and one or more pharmacologically acceptable auxiliaries or excipients."

The only dispute with respect to this term is whether, as Defendants argue, it includes an implied negative limitation that, in order to be "purified and isolated," the compound cannot contain any pharmacologically acceptable auxiliaries or excipients. Defendants argue that this limitation is required in order to give meaning to the term "isolated." (D.I. 156 at 7). Defendants further argue that Plaintiffs' proposed construction is an attempt to improperly broaden the scope of the claim, as well as an attempt to rescue dependent claim 18, which Defendants contend is invalid for improper dependency under their proposed construction. (*Id.* at 7-8). Plaintiffs counter that the intrinsic record, including the patent's other claims, the specification, and the prosecution history all support their argument that the phrase "purified and isolated" does not exclude inactive pharmaceutical ingredients. (D.I. 144 at 8).

I agree with Plaintiffs. Claim 18 reads, "A pharmaceutical composition comprising the compound of claim 14 and one or more pharmacologically acceptable auxiliaries or excipients." Any compound that meets the limitations of claim 18 must also meet the limitations of the necessarily broader claim 14. It seems to me that this means that Defendants' proposed limitation is inconsistent with the claims themselves. Defendants counter that it is claim 18 that is invalid because it "does not incorporate 'all the limitations of the claim to which it refers' and further fails to 'specify a further limitation of the subject matter claimed' in claim 14." (D.I. 156 at 15) (quoting 35 U.S.C. § 112, paragraph 4 (2010)). I disagree. Claim 18 requires that the compound of claim 14 be incorporated into a pharmaceutical composition. This is quite clearly an additional limitation

not present in claim 14. Furthermore, the only way to conclude that claim 18 does not incorporate all of claim 14's limitations is to adopt Defendants' implied negative limitation that "isolated" requires that the compound be separate from any other compounds or ingredients. This argument fails, however, because the term must be construed in the context of the patent, including the other claims, rather than in isolation as Defendants propose. I find no support for Defendants' argument in the intrinsic evidence.

The specification additionally supports Plaintiffs' position. For example, the patent teaches a method for preparing a compound, specifying that the product of the reaction "can be isolated by silica gel chromatography" from "the reaction mixture." ('456 patent at 53:35-36). This usage is inconsistent with Defendants' much more restrictive limitation that the compound must be kept isolated and separate from any other compounds. Rather, it seems clear to me that the patent uses the word "isolated" to mean separated from synthesis-related compounds existing in the reaction mixture. Furthermore, the very same example uses the word "purified" in a similar context, specifying that, "The product is purified by silica gel chromatography." (*Id.* at 53:5-6). It seems to me that "purified and isolated" are used as a compound phrase in claim 14 and that, taken together, the phrase simply means that the compound is free of impurities and synthesis related compounds. The intrinsic evidence does not support giving the word "isolated" any additional meaning as Defendants propose. Therefore, I will adopt Plaintiffs' proposed construction.